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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,385	03/29/2004	Masahiro Okuda	Q80589	3080

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

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11/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/811,385	**Applicant(s)** OKUDA ET AL.	
	Examiner Yunsoo Kim	**Art Unit** 1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 112 1st, new matter.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *6,8,9,12 and 15-22*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because:
Claims 6, 8, 9 and 15-22 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 5,834,223, of record, as is evidenced by Galli et al. (Blood, 1999, vol. 93(7): 2149-2157), of record, in view of U.S. Pat. No. 4,914,040, of record, for the reasons set forth in the office action mailed 7/12/07.

Applicants' arguments filed on 10/26/07 have been fully considered but they were not persuasive.

Applicants traversed the rejection based on that the '223 patent does not teach or suggest a coagulation time reagent containing a first composition for coagulation and an anti-phospholipid antibody capturing component that is selected from the group consisting of antibodies, plasma, serum, and immunoglobulin, where the anti-phospholipid capturing component is derived from vertebrate animals other than humans. Therefore, the combination of teachings is not obvious.

Contrary to Applicants' arguments, the '223 patent teaches a reagent for measuring coagulation time comprising a composition for coagulation such as procoagulant (col. 3-4 overlapping paragraph, claims 1, 9-10, in particular), the procoagulant comprises calcium ions, phospholipids and ellagic acid as an activator (col. 4, line 54, in particular) and the human plasma or blood samples are used (Examples 1-9, in particular). The referenced reagent for measuring coagulation time is comparable to the claimed first composition without the non human derived anti-phospholipid antibody capturing component.

The '223 patent further teaches various phospholipid/calcium based procoagulant test system for measuring clotting time such as RVVT using viper venom, KCT using kaolin or CSCT using silica (col. 4, lines 38-61, in particular).

Moreover, the '223 patent teaches the reagent for measuring coagulant time can be packaged in a kit in separate containers (col. 6, lines 39-53) and the reagent samples can be prepared differently in the presence or absence of the test constituents/controls and with the different concentrations (col. 5, lines 18-45, in particular).

As is evidenced by Galli et al., the phospholid/calcium based assays such as RVVT, KCT and CSCT detect phospholipid antibody and further indicate presence of human lupus anticoagulant (p. 2152-2153, Tables 4-5, in particular).

Claims 15-17, 21 and 22 are included in this rejection because the '223 patent teaches packaging calcium ions separately in a kit (col. 6, lines 39-50, in particular) and calcium is being added lastly before measuring the clotting time (claim 1, in particular).

Claim 9 is included in this rejection because packaging the preparatory reagents based on the presence or absence of "antibodies, plasma, serum and immunoglobulin derived from vertebrate animals other than human", (non-human antibody, thereafter) and further packaging based on the presence or absence of the calcium ions are well within the purview of the optimization of the ordinary skill in the art.

The '223 patent does not teach use of non-human antibody in a reagent for measuring coagulation time and the deficiency is cured by the '040 patent.

As discussed in the office action mailed 7/12/07, the '040 patent teaches that any assays involving in human blood samples have interfering factors. The interfering factors compete with analytes in the test samples and interfere with specificity and sensitivity (false negative or false positive) of the assays (col. 1, lines 6-45, in particular).

The '040 patent further teaches that the addition of antibody from the different source from the test material (e.g. a test material of human blood would require antibody from non-human source) avoid the competition of the interfering factors (col. 3-4, col. 4, lines 30-34, in particular) as a rule. Thus, the elimination of the competition between interfering factors and the analyte of test samples improves the assay system (col. 2, lines 60-65, in particular).

It would have been obvious to one of the ordinary skill in the art at the time the invention was made to add non-human antibody (antibody from the different source from the test material) as taught by the '040 patent in the reagent for measuring coagulation time as taught by the '223 patent.

One of the ordinary skill in the art at the time the invention was made would have been motivated to do so because addition of the secondary antibody from the different source from the test material eliminates competition between the interfering factors from the human blood and the analyte of the assay system and improves the assay system as taught by the '040 patent.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

As one cannot show nonobviousness by attacking references individually where the rejections are based on the combinations of references. See MPEP 2145(d). Therefore, the combination of teachings remains obvious..

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November 14, 2007

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